FEB 2 6 2014

5. 510(K) SUMMARY

Submitter's Name:	Emerge Medical
Submitter's Address:	720 S. Colorado Blvd. Suite 550-S Denver, CO 80246
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Authorized Contact Name:	Michelle Potvin
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Contact's Email:	michelle.potvin@emergemedical.com
Date Summary was Prepared:	November 15th, 2013
Trade or Proprietary Name:	Emerge Medical Bone Plate System
Common or Usual Name:	Single/multiple component metallic bone fixation appliances and accessories (§888.3030) Smooth or threaded metallic bone fixation fastener (§888.3040)
Classification:	Class II per 21 CFR §888.3030 Class II per 21 CFR §888.3040
Product Codes:	HRS, HWC
Classification Panel:	Orthopedic and Rehabilitation Devices Panel

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Emerge Medical Bone Plate System consists of stainless steel and titanium components including locking plates, cortex screws, cancellous screws, and washers. The plates are available in a variety of lengths with the number of holes varying depending on plate length. The screws and plates are provided non-sterile.

The device description for the Emerge Medical Bone Plate System is similar to that of the predicate devices listed in Table 5.1 Predicate Devices.

TECHNOLOGICAL CHARACTERISTICS

The fundamental scientific principles and technological characteristics, including the intended use, material, general design, and sizes of the device are equivalent to the predicate device.

INDICATIONS FOR USE

The indications for the Emerge Medical Bone Plate System are as follows for the four sub-systems:

The Emerge Medical Locking Mini Fragment System is intended for fixation of fractures, osteotomies, non-unions, deformations, revisions, replantations, of small bones and bone fragments including tarsals, metatarsals, carpals, metacarpals, phalanges, calcaneus, hand, wrist, foot, and ankle, including in osteopenic bone.

The Emerge Medical Non-Locking Mini Fragment System is intended for fixation of fractures, osteotomies, non-unions, deformations, revisions, replantations of small bones and bone fragments including tarsals, metatarsals, phalanges, calcaneus, hand, wrist, foot, and ankle, including in osteopenic bone.

The Emerge Medical Non-Locking Modular Hand System is intended for fixation of fractures, osteotomies, non-unions, deformations, revisions, replantations, of bones and bone fragments including phalanges, hand, and wrist, including in osteopenic bones.

The Emerge Medical Modular Foot System is intended for fixation of fractures, osteotomies, non-unions, deformations, revisions, replantations, of bones and bone fragments including tarsals, metatarsals, calcaneus, foot, and ankle, including in osteopenic bone.

The indications for use for the Emerge Medical Bone Plate System is similar to that of the predicate devices listed in Table 5.1 Predicate Devices.

Table 5.1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer
K030310	Synthes Modular Hand System	Synthes
K001941	Synthes Modular Foot System	Synthes
K020401	Synthes Calcaneal Plate	Synthes
K063049	Synthes Mini Fragment LCP System	Synthes
K011335	Synthes One-Third DCL Plate	Synthes
K010321	Synthes Modular Foot System-2.7mm Module	Synthes

PERFORMANCE DATA

The Emerge Medical Bone Plate System has been tested in the following test modes:

- Dynamic four-point bending per ASTM F382-99 (2008)
- Static torsion testing per ASTM F543-13 (2013)
- Static axial pullout per ASTM F543-13 (2013)

The results of this non-clinical testing show that the strength of the Emerge Medical Bone Plate System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Emerge Medical Bone Plate System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2014

Emerge Medical
Ms. Michelle Potvin
Vice President of Quality Assurance
720 South Colorado Boulevard, Suite 550-S
Denver, Colorado 80246

Re: K133536
Trade/Device Name: Emerge Medical Bone Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: December 2, 2014
Received: December 4, 2014

Dear Ms. Potvin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K133536

4. INDICATIONS FOR USE STATEMENT

Device Name: Emerge Medical Bone Plate System

The indications for the Emerge Medical Bone Plate System are as follows for the four sub-systems:

The Emerge Medical Locking Mini Fragment System is intended for fixation of fractures, osteotomies, non-unions, deformations, revisions, replantations, of small bones and bone fragments including tarsals, metatarsals, carpals, metacarpals, phalanges, calcaneus, hand, wrist, foot, and ankle, including in osteopenic bone.

The Emerge Medical Non-Locking Mini Fragment System is intended for fixation of fractures, osteotomies, non-unions, deformations, revisions, replantations of small bones and bone fragments including tarsals, metatarsals, phalanges, calcaneus, hand, wrist, foot, and ankle, including in osteopenic bone.

The Emerge Medical Non-Locking Modular Hand System is intended for fixation of fractures, osteotomies, non-unions, deformations, revisions, replantations, of bones and bone fragments including phalanges, hand, and wrist, including in osteopenic bones.

The Emerge Medical Modular Foot System is intended for fixation of fractures, osteotomies, non-unions, deformations, revisions, replantations, of bones and bone fragments including tarsals, metatarsals, calcaneus, foot, and ankle, including in osteopenic bone.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D Frank -S

Division of Orthopedic Devices